ORIGINAL

# TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

| DOCUMENT DESCRIPTION | DOCUMENT CONTROL NUMBER | DATE RECEIVED |
|---|---|---|
| 8EHQ-12- 18777 | 88120000320 | 8/10/12 |

COMMENTS:

DOES NOT CONTAIN CBI

347773



PERGAN
The Peroxide Company

Pergan Marshall, LLC
710-B Bussey Road
Marshall, TX 75670
(903) 938-5141
(903) 935-1298

August 06, 2012

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004

Cc: Akzo Nobel Polymer Chemicals bv
Arkema France
United Initiators GmbH & Co. KG


**SUBJECT: TSCA 8(e) Notice**

Dear TSCA Section 8(e) Coordinator:

On behalf of Pergan Marshall LLC we are submitting final histopathological results of an oral 28-day study of an OECD 407 Repeated Dose 28-Day Oral Toxicity Study in rats with bis(3,5,5-trimethylhexanoyl)peroxide (CAS 3851-87-4) 75% in isododecane (CAS 93685-81-5), as stabiliser. The study was sponsored by Pergan GmbH.

Groups of ten rats (five females and five males) were dosed at 100, 300 and 1000 mg/kg bw by oral gavage. The test substance was dissolved in *Paraffinum perliquidum*. A control group received *Paraffinum perliquidum* alone.

All animals survived the treatment period. At terminal sacrifice, the incidence of pale liver observation was increased in a dose-related manner in groups treated at 300 and 1000 mg/kg/day, and pale and enlarged kidney was found in one male treated at 300 mg/kg/day. Pale liver was observed in 3/5 males and 1/5 females treated at 300 mg/kg/day and in 5/5 males and 2/5 females treated at 1000 mg/kg/day. This finding corroborated the higher liver weights recorded in these groups (males: $p < 0.001$ at 300 and 1000 mg/kg/day; females: $p < 0.01$ at 1000 mg/kg/day). In view of the organ weight and histological findings seen, these observations were considered test item-related.
Histopathological findings considered to be test item-related were seen in the liver, kidney, seminal vesicle, coagulating gland and thymus. The kidney changes were considered to be of no toxicological relevance for humans.
In the liver, minimal or mild diffuse hepatocellular hypertrophy was noted in a dose-related manner in both sexes treated at 300 and 1000 mg/kg/day. A minimal to moderate diffuse hepatocellular microvacuolation was observed in the same groups, without being dose-related, and also in 1/5 female treated at 100 mg/kg/day. In addition, in males treated at 1000 mg/kg/day, a minimal degree of hepatocellular single cell death (mainly in the centrilobular zones of hypertrophy) was seen.
In the kidney of males only, hyaline droplets in corticotubular cells were seen in a dose related manner in the groups treated at 100, 300 and 1000 mg/kg/day. These were considered to represent α2-microglobulin. They were associated with multifocal debris-filled tubules in the inner cortex and with diffuse dilation of medullary tubules, considered to be most likely the consequence of excretion of degenerated and exfoliated corticoepithelial cells. Furthermore, at 300 and 1000 mg/kg/day in males, minimal multifocal corticotubular degeneration was also observed. As the renal storage of α2-microglobulin is commonly recognized to be a male rat-specific event, its test item-related increase in severity and associated secondary renal changes in this study are regarded to be of no relevance for man.


CONTAINS NO CB

At 1000 mg/kg/day, in the seminal vesicle and coagulating gland, the incidence of epithelial single cell death was increased, and in the thymus, in both sexes and confirming minor weight decreases, a minimal tendency towards more prominent atrophy/regression was noted.

Other parameters measured in the study have not yet been analysed.

Please contact me at 903-934-7757 if you have any questions regarding this letter.

Sincerely,

Jan Fulton

From: (903) 938-5141
Donna Sellers
Pergan Marshall, LLC
710-B BUSSEY ROAD

MARSHALL, TX 75670

Origin ID: GGGA

FedEx Express

J1220120718032S

Ship Date. 07AUG12
ActWgt: 0 5 LB
CAD: 1045602/INET3300

Delivery Address Bar Code

SHIP TO: (214) 665-7193 BILL SENDER

**EPA EAST ROOM 6428 ATTN SECTION 8(E**
**US ENVIRONMENTAL PROTECTION AGENCY**
**1201 CONSTITUTION AVE NW**

**WASHINGTON, DC 20460**

Ref # LTR FROM GMBH
Invoice #
PO #
Dept #

WED - 08 AUG A1
STANDARD OVERNIGHT

TRK# 7938 7718 7151
0201

**XC RDVA**

20460
DC-US
DCA

515G2/0C34/AA44

**After printing this label**:
1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

**Warning** Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges along with the cancellation of your FedEx account number.
Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex com.FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery,misdelivery,or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim.Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental,consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss.Maximum for items of extraordinary value is $500, e g. jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx Service Guide